to about 70% of the total weight of the composition and said one or more gelling agents is about 5% to about 20% of the total weight of the composition.

9. A delayed-onset composition comprising a core and a coating wherein said coating is dry-compressed and comprises excipients comprising one or more prolamins and one or more gelling agents, wherein said one or more prolamins is about 30% to about 100% of the total weight of the coating and said one or more gelling agents is about 0% to about 20% of the total weight of the coating.

A marked-up version of the above amended claims pursuant to 37 C.F.R. 1.121(c)(1)(ii) is attached for the Examiner's review as Exhibit A.

REMARKS

Claims 1 and 3-19 appear in this application for the Examiner's review and consideration. The amendments to claims 1and 9 are fully supported by the specification and the claims as originally filed. Therefore, there is no issue of new matter.

Support for Claim Amendments:

Support for the amendments to claim 1 can be found in Examples 1-3 of the specification as originally filed.

Support for the amendments to claim 9 can be found in Example 4 of the specification as originally filed.

A complete clean listing of pending claims 1 and 3-19 is attached for the Examiner's convenience as Exhibit B pursuant to 37 C.F.R. 1.121(c)(1)(iii).

THE REJECTIONS UNDER 35 U.S.C. § 102

Claims 1, 2-8 and 18

Claims 1 and 3-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by International Patent Application No. WO 95/28916 ("Baichwal") for the reasons set forth on page 2 of the Office Action. Applicants traverse.

Claim 1and therefore claims 2-8 and 18, which depend from claim 1, have been amended to recite that the one or more prolamins are present in the sustained-release composition from about 30% to about 70% by weight of the total composition and the one or more gelling agents are present in the sustained-release composition from about 5% to about 20% of the total weight of the composition.

Baichwal states that the hydrophobic material (corresponds to the present application's prolamins) may be present in the sustained-release matrix from about 1% to about 20% by weight. (Page 8, lines 1-10). Additionally, Baichwal teaches that the sustained-release matrix is present in Examples 1-3 at 80.8% by weight. (Page 15, lines 1-33). Thus, the hydrophobic material would be present in Example tablets 1-3 from about 0.1% to about 16% by total weight of the tablet. Even if one of skill in the art, however unlikely, were to prepare a tablet consisting of 100% of the sustained-release matrix of Baichwal the hydrophobic material would be present from about 1% to about 20% by total weight of the tablet. Further, Baichwal states that "[t]he amount of hydrophobic material incorporated into the sustained release matrix is that which is effective to slow the hydration of the gums without disrupting the hydrophilic matrix formed upon exposure to an environmental fluid." (Page 7, line 33 to page 8, line 1).

Clearly, the claims of the present invention, which teach hydrophobic, sustained-release compositions comprising from about 30% to about 70% prolamins (hydrophobic material), by total weight, are not anticipated by Baichwal. Therefore, applicants respectfully request that the Examiner withdraw the rejections of claims 1, 2-8 and 18 under 35 U.S.C. § 102(b).

Claims 9-17 and 19

Claims 9-17 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Baichwal for the reasons set forth on page 2 of the Office Action. Applicants traverse.

Claim 9 and therefore claims 10-17 and 19, which depend from claim 9, have been amended to recite that the one or more prolamins are present in the sustained-release coating from about 30% to about 100% by weight.

Baichwal states that the hydrophobic material (corresponds to the present application's prolamins) may be present in the sustained-release matrix from about 1% to

about 20% by weight. (Page 8, lines 1-10). Additionally, Baichwal teaches that the sustained-release matrix is present in Examples 1-3 at 80.8% by weight. (Page 15, lines 1-33). Thus, the hydrophobic material would be present in Example tablets 1-3 from about 0.1% to about 16% by total weight of the tablet. Even if one of skill in the art, however unlikely, were to prepare a tablet consisting of 100% of the sustained-release matrix of Baichwal the hydrophobic material would be present from about 1% to about 20% by total weight of the tablet. Further, Baichwal states that "[t]he amount of hydrophobic material incorporated into the sustained release matrix is that which is effective to slow the hydration of the gums without disrupting the hydrophilic matrix formed upon exposure to an environmental fluid." (Page 7, line 33 to page 8, line 1).

Clearly, the claims of the present invention, which teach hydrophobic, delayed-onset compositions comprising from about 30% to about 100% prolamins (hydrophobic material), by weight of the coating, are not anticipated by Baichwal. Therefore, applicants respectfully request that the Examiner withdraw the rejections of claims 9, 10-17 and 19 under 35 U.S.C. § 102(b).

THE REJECTIONS UNDER 35 U.S.C. § 103

Claims 1 and 3-19 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Baichwal for the reasons set forth on pages 3 and 4 of the Office Action. Applicants traverse.

Claim 1and therefore claims 2-8 and 18, which depend from claim 1, have been amended to recite that the one or more prolamins are present in the sustained-release composition from about 30% to about 70% by weight of the total composition and the one or more gelling agents are present in the sustained-release composition from about 5% to about 20% of the total weight of the composition. Additionally, claim 9 and therefore claims 10-17 and 19, which depend from claim 9, have been amended to recite that the one or more prolamins are present in the sustained-release coating from about 30% to about 100% by weight.

Baichwal teaches a hydrophilic sustained-release excipient for use in oral solid dosage forms that comprises from about 15% to about 30% or more by weight of a heteropolysaccharide gum (corresponds to the gelling agent of the present application), an

effective amount of a cationic cross-linking agent and optionally a hydrophobic material (corresponds to the prolamin of the present application) in an amount effective to slow the hydration of the gum without disrupting the hydrophilic matrix formed by the heteropolysaccharide when the formulation is exposed to fluids in an environment of use. (Page 2, lines 11-19 and page 7, lines 18-23). The hydrophobic material is present in the sustained-release matrix from about 1% to about 20% by weight. Further, Baichwal teaches that the sustained-release matrix is present in Example tablets 1-3 at 80.8% by weight. Thus, the hydrophobic material is present from about 0.1% to about 16% by total weight of Example tablets 1-3. Even if one of skill in the art, however unlikely, were to prepare a tablet consisting of 100% of the sustained-release matrix of Baichwal the hydrophobic material would be present from about 1% to about 20% by total weight of the tablet.

One of ordinary skill in the art at the time of the invention would not have been led by the teachings of Baichwal, which state that the optional hydrophobic material of the sustained-release matrix is present in such an amount that it does not disrupt the hydrophilic matrix formed by the heteropolysaccharide in the presence of environmental fluids (Page 7, lines 18-23), to prepare compositions wherein the hydrophobic material is present in quantities greater than the quantity of heteropolysaccharide. Conversely, the claims of the present invention recite sustained-release and delayed-onset compositions wherein the prolamin (corresponds to the hydrophobic material of Baichwal) is present from about 30% to about 70% by total weight of the composition and from about 30% to about 100% by total weight of the coating, respectively.

Additionally, in the Office Action, the Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to "vary the ingredient (the prolamin, gelling agents, active agents and additional excipients) to achieve the same expected result." (Page 3). Applicants argue that it would not have been obvious to one of ordinary skill in the art at the time of the invention to formulate sustained-release or delayed-onset compositions wherein the prolamin (hydrophobic material) is present in amounts of 30% or greater by weight. Baichwal teaches that too much hydrophobic material will disrupt the hydrophilic matrix that is disclosed; whereas, the claims of the present invention recite compositions wherein the prolamin (hydrophobic material) is always present in an amount greater than the amount of gelling agent (heteropolysaccharide).

One of skill in the art at the time of the invention would not have been led to create the hydrophobic, sustained-release and hydrophobic, delayed-onset formulations of the present application after reading the hydrophilic, sustained release compositions disclosed in Baichwal. Therefore, applicants respectfully request that the Examiner withdraw the rejections of claims 1 and 3-19 under 35 U.S.C. § 103(a).

Applicants thus submit that the entire application is now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree with the Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

A fee for a three-month extension of time is believed to be due for the filing of this amendment. A separate Fee Sheet for the three-month extension of time is filed concurrently herewith. Should any additional fees be found to be due, please charge the required amount to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date October 15, 2002

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Enclosure

EXHIBIT A

Marked-up version of the above amended claims pursuant to 37 C.F.R. 1.121(c)(1)(ii).

1. A sustained-release composition comprising a core wherein said core comprises one or more active agents in combination with excipients comprising one or more prolamins and one or more gelling agents, wherein said one or more prolamins is about 30% to about 70% of the total weight of the composition and said one or more gelling agents is about 5% to about 20% of the total weight of the composition [0.5 wt.% to about 50 wt.% of the combined weight of said one or more prolamins and said one or more gelling agents].

9. A delayed-onset composition comprising [comprises] a core and a coating wherein said coating is dry-compressed and comprises excipients comprising one or more prolamins and one or more gelling agents, wherein said one or more prolamins is about 30% to about 100% of the total weight of the coating and said one or more gelling agents is about 0% to about 20% of the total weight of the coating [0.5 wt.% to about 50 wt.% of the combined weight of said one or more prolamins and said one or more gelling agents].